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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,315 | 10/17/2001 | Horst Fischer | 200116.403D1 | 6566 |

500 7590 04/25/2005

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| EXAMINER |
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OWENS JR, HOWARD V

| ART UNIT | PAPER NUMBER |
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1623

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,315

Applicant(s)

FISCHER ET AL.

Examiner

Howard V. Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64-67 is/are allowed.
- 6) ☐ Claim(s) 59-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

The following is in response to the amendment filed 12/1/04:

An action on the merits of claims 59 - 67 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 35 U.S.C. §101, 112 and 102 rejections of record have been withdrawn in view of applicant's amendment to the claims.

Double Patenting

The rejection of claims 59-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of U.S. Patent No. 6,329,422 ('422) is maintained for the reasons of record set forth below.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 32 of '422 is generic to all that is recited in claims 59-63. That is claims 59-63 fall entirely within the scope of claim 32.

Claims 59 - 63 are drawn to one or more flavones or isoflavones, wherein the species of flavones or isoflavones is set forth, i.e, genistein, quercetin, kaempferol, apigenin, etc. capable of stimulating chloride secretion; (b) one or more of: (i) a compound that increases expression of a CFTR in an epithelial cell; (ii) a chemical

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chaperone that increases trafficking of a CFTR to a plasma membrane in a plasma membrane in an epithelial cell.

Claim 32 of '422 is broadly drawn to a composition comprising one or more flavones or isoflavones, capable of stimulating chloride secretion; (b) one or more of: (i) a compound that increases expression of a CFTR in an epithelial cell; (ii) a chemical chaperone that increases trafficking of a CFTR to a plasma membrane in a plasma membrane in an epithelial cell. The flavones or isoflavones set forth in claims 59-63 are clearly species of the generic flavones/isoflavones set forth in claim 32 of '422, wherein they are anticipated as species of that genus and the motivation to use them in the composition is still retained as they are recognized as only those flavones/isoflavones capable of stimulating chloride secretion.

Allowable Subject Matter

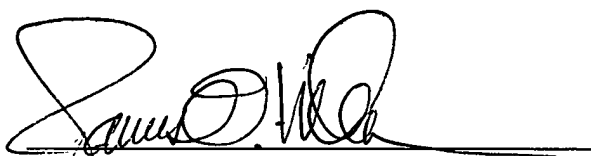
Claims 64 - 67 appear to contain subject matter allowable over the prior art cited supra because the prior art of record does not teach or fairly suggest the method of treating cystic fibrosis using the combination of the specific CFTR expression and trafficking agents in combination with flavones or isoflavones.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Howard V. Owens
Patent Examiner
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A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.